

WHAT IS CLAIMED IS:

1. A method of monitoring a concentration of an oxidative gas or vapor in a diffusion-restricted region in fluid communication with a sterilization chamber during a sterilization process, the method comprising:

5 providing a concentration monitor responsive to the oxidative gas or vapor by generating a parameter, the concentration monitor comprising a first temperature sensing device and a chemical substance reactive with the oxidative gas or vapor to produce heat, the first temperature sensing device coupled to the chemical substance and responsive to the heat produced by the chemical
10 substance and the oxidative gas or vapor by generating a first signal, the parameter generated in response to the first signal;

placing at least a portion of the concentration monitor comprising the chemical substance within the diffusion-restricted region;

introducing the oxidative gas or vapor into the sterilization chamber; and

15 monitoring the parameter generated by the concentration monitor during the sterilization process, thereby monitoring the concentration of the oxidative gas or vapor within the diffusion-restricted region during the sterilization process.

2. The method of Claim 1, wherein the concentration monitor further
20 comprises a second temperature sensing device which generates a second signal, and the parameter is generated in further response to the second signal.

3. The method of Claim 1, wherein the first temperature sensing device comprises a first thermocouple junction and the first signal comprises a first voltage.

4. The method of Claim 3, wherein the concentration monitor further
25 comprises a second thermocouple junction which generates a second voltage, and the parameter is generated in further response to the second voltage.

5. The method of Claim 4, wherein the second thermocouple junction is coupled in series to the first thermocouple junction, and the parameter is generated in further response to a net voltage generated across the first and second thermocouple
30 junctions in response to the first and second voltages.

6. The method of Claim 1, wherein monitoring the parameter further comprises converting the parameter generated by the concentration monitor to a measurement of the concentration of the oxidative gas or vapor in the diffusion-restricted region.

5 7. The method of Claim 1, wherein the oxidative gas or vapor comprises hydrogen peroxide.

8. The method of Claim 1, wherein the diffusion-restricted region comprises a region inside a test pack.

10 9. The method of Claim 1, wherein the diffusion-restricted region comprises a region inside a lumen.

10. The method of Claim 9, wherein the lumen is inside a container in fluid communication with the sterilization chamber.

11. The method of Claim 1, wherein the diffusion-restricted region comprises a region inside a process challenge device (PCD).

15 12. The method of Claim 11, wherein the PCD is adjustable to vary a diffusion path between the region inside the PCD and the sterilization chamber and the method further comprises adjusting the PCD to mimic a second diffusion-restricted region within the load.

20 13. The method of Claim 1, wherein the diffusion-restricted region comprises a region inside a second chamber in fluid communication with the sterilization chamber.

14. The method of Claim 1, wherein the diffusion-restricted region is designed so as to mimic the diffusion of the oxidative gas or vapor to a second diffusion-restricted region of the load.

25 15. The method of Claim 1, wherein the diffusion-restricted region comprises a region inside a packaged device.

16. The method of Claim 1, further comprising placing a load into the sterilization chamber and determining a suitability of the load.

30 17. The method of Claim 16, wherein the concentration monitor is coupled to a control feedback mechanism which controls a process parameter of the sterilization

system, and the method further comprises controlling the process parameter in response upon determining the suitability of the load.

18. The method of Claim 16, further comprising aborting the sterilization process upon determining that the load is not suitable.

5 19. The method of Claim 16, further comprising introducing additional oxidative gas or vapor into the sterilization chamber upon determining that the load is not suitable.

20. The method of Claim 16, further comprising activating an alarm upon determining that the load is not suitable.

10 21. The method of Claim 16, wherein determining the suitability of the load comprises defining a minimum concentration level of the oxidative gas or vapor in the diffusion-restricted region corresponding to a suitable load.

15 22. The method of Claim 16, wherein determining the suitability of the load comprises defining a maximum rate of decrease of the concentration of the oxidative gas or vapor in the diffusion-restricted region corresponding to a suitable load.

23. The method of Claim 16, wherein determining the suitability of the load comprises defining a minimum rate of increase of the concentration of the oxidative gas or vapor in the diffusion-restricted region corresponding to a suitable load.

20 24. The method of Claim 16, wherein determining the suitability of the load comprises defining a minimum time-integrated concentration of the oxidative gas or vapor in the diffusion-restricted region corresponding to a suitable load.

25. An apparatus for monitoring a concentration of an oxidative gas or vapor in a sterilization chamber during a sterilization process, the apparatus comprising:

25 a diffusion-restricted region in fluid communication with the sterilization chamber; and

30 a concentration monitor responsive to the oxidative gas or vapor by generating a parameter, at least a portion of the concentration monitor within the diffusion-restricted region; the concentration monitor comprising a first temperature sensing device and a chemical substance reactive with the oxidative gas or vapor to produce heat, the first temperature sensing device coupled to the chemical substance and responsive to the heat produced by the chemical

substance and the oxidative gas or vapor by generating a first signal, the parameter generated in response to the first signal.

26. The apparatus of Claim 25, wherein the first temperature sensing device comprises a first thermocouple junction and the first signal comprises a first voltage.

5 27. The method of Claim 25, wherein the concentration monitor further comprises a second temperature sensing device which generates a second signal, and the parameter is generated in further response to the second signal.

10 28. The method of Claim 27, wherein the second temperature sensing device comprises a second thermocouple junction and the second signal comprises a second voltage.

29. The method of Claim 28, wherein the second thermocouple junction is coupled in series to the first thermocouple junction, and the parameter is generated in further response to a net voltage generated across the first and second thermocouple junctions in response to the first and second voltages.